Patent Office on December 4, 2002, with the Supplemental Disclosure Statement submitted to the Patent Office on December 4, 2002. However, in order to accommodate the Examiner, Applicant includes a copy of the Supplemental Information Disclosure Statement and attachments therein, including copies of the references and English summaries of the foreign documents.

In paragraph V(i) of the Action, the Examiner objects to the use of the term "Trilon B" in the application, and states the term should be capitalized wherever it appears and be accompanied by generic terminology. In response, Applicant amends the specification herein to refer to "Trilon B" in capital letters and with the appropriate generic terminology, as "TRILON B® (disodium salt of ethylenediaminetetraacetic acid)", or, after pointing out that the term "ethylenediaminetetraacetic acid" means "EDTA", as "TRILON B® (disodium salt of EDTA)".

In paragraph V(ii) of the Action, the Examiner objects to page 7 line 11 as having a typographic error, wherein the number "10" is missing. In response, Applicant amends the application on page 7 line 11 to include the number "10". Applicant notes that page 7 sets forth the abstract of the application.

In paragraph VI of the Action, the Examiner rejects claims 14-20 as indefinite for containing the term "Pa*s" and the term "Trilon B". In response, Applicant amends the claims so that the term "Pa*s" is replaced by the term "Pascal·second", and refers to the term Trilon B as "TRILON B® (disodium salt of ethylenediaminetetraacetic acid)".

In view of the foregoing discussion and amendments to the specification set forth herein, Applicant respectfully submits all of the present objections are overcome and requests that the Examiner allow the application so that it may proceed to grant.

Respectfully submitted,

May 5, 2003

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DOCKET: CU-2642 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	Petr Jakovlevich Gaponyuk et al.	)
		)
SERIAL NO:	09/936,470	) Group Art Unit: 1646
		)
FILED:	December 18, 2001	) Examiner: Ruixiang Li
TITLE:	ANTIVIRAL AGENT IN THE FORM OF NOSE DROPS	

THE ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

MARKED VERSION OF AMENDED CLAIMS 14, 15, 17 AND 18

14. An antiviral drug presented as nasal drops comprising genetically engineered alpha, beta or gamma interferon, at least one biocompatible polymer selected from the group consisting of polyvinyl pyrrolidone and polyethylene oxide, and a biocompatible antioxidant, the drug viscosity being 11 – 300 **[Pa*s]** **Pascal·second**.

15. The antiviral drug of claim 14 wherein the antioxidant is **[Trilon B]** **TRILON B®** **(disodium salt of ethylenediaminetetraacetic acid)**.

17. An antiviral drug presented as nasal drops comprising per ml of a buffered saline solution:

a. genetically engineered alpha, beta or gamma interferon	1,000 – 300,000 IU
b. at least one biocompatible polymer selected from the group consisting of polyvinyl pyrrolidone and polyethylene oxide	0.005 – 0.714 g
c. antioxidant	0.0001 – 0.0008 g

the drug viscosity being 11 – 300 **[Pa*s]** **Pascal·second**.

18. The antiviral drug of claim 17 wherein the antioxidant is **[Trilon B]** **TRILON B®** **(disodium salt of ethylenediaminetetraacetic acid)**.

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SERIAL NO:	09/936,470	) Group Art Unit: 1646
		)
FILED:	December 18, 2001	) Examiner: Ruixiang Li

TITLE: ANTIVIRAL AGENT IN THE FORM OF NOSE DROPS

THE ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

~~CLEAN VERSION~~ OF AMENDED CLAIMS 14, 15, 17 AND 18

~~14.~~ 1. An antiviral drug presented as nasal drops comprising genetically engineered alpha, beta or gamma interferon, at least one biocompatible polymer selected from the group consisting of polyvinyl pyrrolidone and polyethylene oxide, and a biocompatible antioxidant, the drug viscosity being 11 – 300 Pascal·second.

~~15.~~ 2. The antiviral drug of claim ~~14~~ 1 wherein the antioxidant is TRILON B® (disodium salt of ethylenediaminetetraacetic acid).

~~17.~~ 4. An antiviral drug presented as nasal drops comprising per ml of a buffered saline solution:

a. genetically engineered alpha, beta or gamma interferon	1,000 – 300,000 IU
b. at least one biocompatible polymer selected from the group consisting of polyvinyl pyrrolidone and polyethylene oxide	0.005 – 0.714 g
c. antioxidant	0.0001 – 0.0008 g

the drug viscosity being 11 – 300 Pascal·second.

~~18.~~ 5. The antiviral drug of claim ~~17~~ 4 wherein the antioxidant is TRILON B® (disodium salt of ethylenediaminetetraacetic acid).

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MARKED VERSION OF AMENDED SPECIFICATION

Title

ANTIVIRAL **[AGENT IN THE FORM OF NOSE]** **NASAL** DROPS **COMPRISING RECOMBINANT INTERFERON, A BIOCOMPATIBLE POLYMER, AND AN ANTIOXIDANT**

Page 1, Paragraph 4

In Russia, natural human interferons derived from leukocytes **[has]** **have** been widely used for the treatment and prevention of influenza and acute viral respiratory infections (AVRI) since the late 1960s. This interferon was manufactured from expensive donor blood leukocyte preparations (RU, Patent 2033180, Cl. A 61 K 38/21, 1995. SU, Inventor's Certificate 297296, Cl. A 61 K 36/21, 1977. RU, patent 2108804, Cl. A 61 K 38/21, 1996).

Page 3, Paragraph 3

To solve this problem, we developed an antiviral drug (nasal drops) containing a liquid interferon preparation (a genetically engineered alpha, beta or gamma interferon with viscosity of (1.1 – 30.0) * 10 **[Pa*s]** **Pascal·second**). The antiviral drug contains a

biocompatible polymer, antioxidant, and buffer mixture with the following contents of ingredients per ml buffer mixture:

Genetically engineered interferon	1000 – 50,000 IU
Biocompatible polymer	0.005 – 0.714 g
Antioxidant	0.0001 – 0.0008 g

Page 3, Last paragraph to top of Page 4

[Trilon B] TRILON B® (disodium salt of ethylenediaminetetraacetic acid ("EDTA")) is used as an antioxidant, and polyvinylpyrrolidone and/or polyethylene oxide is used as a biocompatible polymer. The drug described here contains polyvinylpyrrolidone and polyethylene oxide at a ratio of 1:1 – 50.

Page 4, Paragraph 1

DETAILED DESCRIPTION OF THE **[PREFFERED] PREFERRED** EMBODIMENTS

Variant 1. The technology of manufactured this drug (nasal drops) is the same for all variants **[describe] described** below. Prepare solutions of the following ingredients in separate containers: 50% polyethylene oxide, 6% polyvinylpyrrolidone and 10% aqueous **[Trilon B] TRILON B® (disodium salt of EDTA)**. Filter the solutions. Use phosphate-buffered saline as a solvent**[/].** Add these solutions to a manufacturing vessel in the specified sequence, and sterilize. Then add genetically engineered interferon. Mix the ingredients. Dispense the solution into appropriate containers, hermetically seal and label.

Suggested composition of the antiviral drug:

Each milliliter of the buffer mixture contains:

Genetically engineered interferon beta	500,000 IU
Polyvinylpyrrolidone	0.014 g
Polyethylene oxide	0.7 g
[Trilon B] TRILON B® (disodium salt of EDTA)	0.0008 g
Viscosity of solution	30.0*10 **[Pa*s] Pascal·second**

Page 4, Paragraph 2

Variant 2. Proceed as described under Variant 1.

Suggested composition of the antiviral drug:

Each milliliter of the buffer mixture contains:

Genetically engineered interferon alpha	10,000 IU
Polyvinylpyrrolidone	0.01 g
Polyethylene oxide	0.1 g
[Trilon B] TRILON B® (disodium salt of EDTA)	0.0004 g
Viscosity of solution	3.0*10 **[Pa*s] Pascal·second**

Page 5, Paragraphs 1-2

Suggested composition of the antiviral drug:

Each milliliter of the buffer mixture contains:

Genetically engineered interferon gamma	1,000 IU
Polyvinylpyrrolidone	0.05 g
[Trilon B] TRILON B® (disodium salt of EDTA)	0.0001 g
Viscosity of solution	1.1*10 **[Pa*s] Pascal·second**

[REASIBILITY] FEASIBILITY OF INDUSTRIAL-SCALE MANUFACTURE

The antiviral drug (nasal drops) obtained as described in the previous section has the appearance of a clear liquid whose viscosity differs between variants. Laboratory tests performed on cultured animal cells showed that the drug is not toxic and fully conserves its antiviral activity.

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MARKED VERSION OF AMENDED ABSTRACT

The present invention can be used in pharmacology specifically in the preparation of interferon-containing compositions, which are capable of conserving their biological activity and can be administrated intranasally, e.g. in the preparation of nasal drops. This invention essentially refers to an antiviral agent in the form of nasal drops that contains a genetically engineered alpha, beta or gamma interferon with a viscosity of (1.1 – 30.0) * **[Pa*s]** **10 Pascal·second**, a biocompatible polymer and a buffer mixture. The agent may further include an antioxidant, and the ingredients are contained in the following amounts per ml buffer mixture: 1,000 to 5,000 IU of genetically engineered interferon; 0.005 to 0.714 g of biocompatible polymer; and 0.0001 to 0.0008 g of an antioxidant. **[Trilon B]** **TRILON B® (disodium salt of EDTA)** is used as the antioxidant, whereas polyvinylpyrrolidone and/or polyethylene oxide is (are) used as the biocompatible polymer(s) at polyvinylpyrrolidone/polyethylene oxide ratio **[is]** **of** 1:1 - 50.